

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ANDREW SALINGER, Individually and
On Behalf of All Others Similarly
Situated,

Plaintiff,

v.

SAREPTA THERAPEUTICS, INC.,
DOUGLAS S. INGRAM, and SANDESH
MAHATME,

Defendants.

Case No.

CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

Plaintiff Andrew Salinger (“Plaintiff”), individually and on behalf of all other persons similarly situated, by Plaintiff’s undersigned attorneys, for Plaintiff’s complaint against Defendants, alleges the following based upon personal knowledge as to Plaintiff and Plaintiff’s own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiff’s attorneys, which included, among other things, a review of the Defendants’ public documents, conference calls and announcements made by Defendants, United States (“U.S.”) Securities and Exchange Commission (“SEC”) filings, wire and press releases published by and regarding Sarepta Therapeutics, Inc. (“Sarepta” or the “Company”), analysts’ reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons other than Defendants who purchased or otherwise acquired Sarepta securities between September 6, 2017 and August 19, 2019, both dates inclusive (the “Class Period”), seeking to recover damages caused by Defendants’ violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the “Exchange Act”) and Rule 10b-5 promulgated thereunder, against the Company and certain of its top officials.

2. Sarepta was founded in 1980 and is headquartered in Cambridge, Massachusetts. Sarepta focuses on the discovery and development of ribonucleic acid (“RNA”)-based therapeutics, gene therapy, and other genetic medicine approaches for the treatment of rare diseases. Sarepta’s products pipeline includes, among other drug candidates, golodirsen for the treatment of duchenne muscular dystrophy (“DMD”). Golodirsen purportedly binds to exon 53 of dystrophin pre-mRNA, which results in exclusion or skipping of exon during mRNA processing in patients with genetic mutations.

3. On September 6, 2017, pre-market, Sarepta announced positive muscle biopsy results from its 4053-101 study, a Phase 1/2 first-in-human study conducted in Europe to assess the safety, tolerability, pharmacokinetics, and efficacy of golodirsen in twenty-five male subjects with confirmed deletions of the DMD gene amenable to skipping exon 53 (the “4053-101 Study”).

4. According to Sarepta, the 4053-101 Study comprised two parts. In Part 1, twelve patients were randomized to receive a dose titration of golodirsen (eight patients) or placebo (four patients). At the end of Part 1 (dose titration), all twelve patients continued on golodirsen and an additional thirteen patients started golodirsen (Part 2). In Part 2, all twenty-five patients were

treated for an additional forty-eight weeks at the time of muscle biopsy. The analysis included biopsies of the bicep muscle at baseline and on-treatment at the Part 2 Week 48 time point.

5. On February 14, 2019, Sarepta announced that the U.S. Food and Drug Administration's ("FDA") Division of Neurology (the "FDA Neurology Division") had accepted the Company's New Drug Application ("NDA") "seeking accelerated approval for golodirsen (SRP-4053) and provided a regulatory action date of August 19, 2019." According to Sarepta, the Company completed its NDA at the end of 2018 as part of a rolling submission and requested priority review, which was granted. Additionally, the NDA included data from the 4053-101 Study.

6. Throughout the Class Period, Defendants made materially false and misleading statements regarding Sarepta's business, operational and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) golodirsen posed significant safety risks to patients; (ii) consequently, the NDA package for golodirsen's accelerated approval was unlikely to receive FDA approval; and (iii) as a result, Sarepta's public statements were materially false and misleading at all relevant times.

7. On August 19, 2019, post-market, Sarepta announced receipt of a Complete Response Letter ("CRL") from the FDA regarding the Company's NDA seeking accelerated approval of golodirsen for the treatment of DMD. Sarepta disclosed that "[t]he CRL generally cites two concerns: the risk of infections related to intravenous infusion ports and renal toxicity seen in pre-clinical models of golodirsen and observed following administration of other antisense oligonucleotides."

8. On this news, Sarepta's stock price fell \$18.24 per share, or 15.16%, to close at \$102.07 per share on August 20, 2019.

9. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

JURISDICTION AND VENUE

10. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

11. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act.

12. Venue is proper in this Judicial District pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b). Sarepta securities trade on the NASDAQ Stock Market ("NASDAQ"), located within this Judicial District.

13. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

PARTIES

14. Plaintiff, as set forth in the attached Certification, acquired Sarepta securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures.

15. Sarepta is a Delaware corporation with principal executive offices located at 215 First Street, Suite 415, Cambridge, MA. Sarepta securities trade in an efficient market on the NASDAQ under the ticker symbol "SRPT".

16. Defendant Douglas S. Ingram (“Ingram”) has served as Sarepta’s President and Chief Executive Officer at all relevant times.

17. Defendant Sandesh Mahatme (“Mahatme”) has served as Sarepta’s Executive Vice President, Chief Financial Officer at all relevant times.

18. Defendants Ingram and Mahatme are sometimes referred to herein collectively as the “Individual Defendants.”

19. The Individual Defendants possessed the power and authority to control the contents of Sarepta’s SEC filings, press releases, and other market communications. The Individual Defendants were provided with copies of Sarepta’s SEC filings and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. Because of their positions with Sarepta, and their access to material information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public, and that the positive representations being made were then materially false and misleading. The Individual Defendants are liable for the false statements and omissions pleaded herein.

SUBSTANTIVE ALLEGATIONS

Background

20. Sarepta was founded in 1980 and is headquartered in Cambridge, Massachusetts. Sarepta focuses on the discovery and development of RNA-based therapeutics, gene therapy, and other genetic medicine approaches for the treatment of rare diseases. Sarepta’s products pipeline includes, among other drug candidates, golodirsen for the treatment of DMD. Golodirsen

purportedly binds to exon 53 of dystrophin pre-mRNA, which results in exclusion or skipping of exon during mRNA processing in patients with genetic mutations.

21. On September 6, 2017, pre-market, Sarepta announced positive muscle biopsy results from its 4053-101 study, a Phase 1/2 first-in-human study conducted in Europe to assess the safety, tolerability, pharmacokinetics, and efficacy of golodirsen in twenty-five male subjects with confirmed deletions of the DMD gene amenable to skipping exon 53.

22. According to Sarepta, the 4053-101 Study comprised two parts. In Part 1, twelve patients were randomized to receive a dose titration of golodirsen (eight patients) or placebo (four patients). At the end of Part 1 (dose titration), all twelve patients continued on golodirsen and an additional thirteen patients started golodirsen (Part 2). In Part 2, all twenty-five patients were treated for an additional forty-eight weeks at the time of muscle biopsy. The analysis included biopsies of the bicep muscle at baseline and on-treatment at the Part 2 Week 48 time point.

23. On February 14, 2019, Sarepta announced that the FDA Neurology Division had accepted the Company's NDA "seeking accelerated approval for golodirsen (SRP-4053) and provided a regulatory action date of August 19, 2019." According to Sarepta, the Company completed its NDA at the end of 2018 as part of a rolling submission and requested priority review, which was granted. Additionally, the NDA included data from the 4053-101 Study.

Materially False and Misleading Statements Issued During the Class Period

24. The Class Period begins on September 6, 2017, when Sarepta issued a press release, pre-market, announcing positive results from the 4053-101 Study (the "September 2017 Press Release"). The September 2017 Press Release highlighted that golodirsen's results from the 4053-101 Study "achieved statistical significance on all primary and secondary biological endpoints" and "further validate[d] the Company's exon-skipping platform for the treatment of DMD[.]"

without specifying what, if any, safety concerns were indicated by that study. Specifically, the September 2018 Press Release stated, in relevant part:

All 25 participants displayed an increase in skipping exon 53 ($p < 0.001$) over baseline levels, representing a 100 percent response rate as measured by RT-PCR and demonstrating proof of mechanism. Mean dystrophin protein increased to 1.019 percent of normal compared to a mean baseline of 0.095 percent of normal ($p < 0.001$) as measured by Western blot, the primary biological endpoint in the study, representing a 10.7 fold increase from baseline. The study also showed a statistically significant increase in dystrophin immunofluorescence as measured by immunohistochemistry (IHC), the secondary biological endpoint in the study, confirming sarcolemma-associated protein expression and distribution.

Francesco Muntoni, principal investigator for this study . . . said, “All treated boys showed the anticipated exon skipping after treatment and this resulted in a mean increase of dystrophin protein, as measured by Western blot, from 0.095 percent at baseline to 1.019 percent of normal after at least one-year of treatment with golodirsen.”

“These data were also supported by the highly statistically significant increase of dystrophin expression at the sarcolemma, as measured by recently developed validated methodology. This is now the second exon-skipping agent to have shown a statistically significant increase in dystrophin production, validating the exon-skipping approach to treating DMD boys with amenable mutations.”

25. The September 2017 Press Release also quoted Defendant Ingram, who touted “the rigor” with which Defendants designed methods for and executed the 4053-101 Study. Defendant Ingram also stressed how golodirsen validated Defendants’ broad application of the Company’s exon-skipping platform. In short, Defendant Ingram vigorously championed golodirsen after receiving positive indications for its use from the 4053-101 Study, without pausing to address the potential safety concerns associated with the drug, stating, in relevant part:

These data demonstrate statistically significant exon skipping, dystrophin production and localization, which further validate the broad application of our exon-skipping platform and aligns with our strategic imperative to expand and improve the treatment choices for the majority of patients with DMD Additionally, the rigor with which we designed our methods and executed this study speaks to our commitment to continuous improvement and scientific excellence.

26. Finally, the September 2017 Press Release touted golodirsen's use of Sarepta's proprietary phosphorodiamidate morpholino oligomer ("PMO") chemistry and exon-skipping technology, which purportedly allowed golodirsen to skip exon 53 of the gene attributable to DMD. The September 2017 Press Release also noted that golodirsen was one of the drug candidates being evaluated in the Company's ESSENCE study, a global, randomized double-blind, placebo-controlled study evaluating efficacy and safety in patients amenable to skipping exons 45 or 53. Specifically, the September 2017 Press Release stated, in relevant part:

Golodirsen uses Sarepta's proprietary phosphorodiamidate morpholino oligomer (PMO) chemistry and exon-skipping technology to skip exon 53 of the *DMD* gene. Golodirsen is designed to bind to exon 53 of dystrophin pre-mRNA, resulting in exclusion, or "skipping," of this exon during mRNA processing in patients with genetic mutations that are amenable to exon 53 skipping. Exon skipping is intended to allow for production of an internally truncated but functional dystrophin protein.

Golodirsen is one of the investigational candidates currently being evaluated in the ESSENCE study, a global, randomized double-blind, placebo-controlled study evaluating efficacy and safety in patients amenable to skipping exons 45 or 53.

27. On March 1, 2018 Sarepta filed its Annual Report on Form 10-K with the SEC, reporting the Company's financial and operating results for the fiscal year ended December 31, 2017 (the "2017 10-K"). The 2017 10-K reiterated the positive results from the 4053-101 Study, again failing to mention what, if any, safety concerns were associated with drug. Specifically, the 2017 10-K stated, in relevant part:

Golodirsen (SRP-4053). We are enrolling and dosing patients in ESSENCE (Study 4045-301), our phase 3 placebo controlled confirmatory trial in patients who have a confirmed mutation of the DMD gene that is amenable to exon 45 or 53 skipping using casimersen and golodirsen, respectively. Golodirsen, an exon 53-skipping product candidate, is currently in the clinic as part of a Phase 1/2 study. Part I has been completed, and Part II, an open-label portion of this study, is ongoing (Study 4053-101). In September 2017, we announced positive results of an analysis that included biopsies of the bicep muscle at baseline and on-treatment at the Part II, Week 48 time point. The study results demonstrated statistical significance on all primary and secondary biological endpoints. Golodirsen will potentially address one of the most prevalent sets of mutations in DMD that are

amenable to exon-skipping. We have recently announced that we are targeting a meeting with the FDA in the first quarter of 2018 to discuss golodirsen.

28. The 2017 10-K also contained merely generic, boilerplate representations concerning the risk that Sarepta's clinical studies could fail to demonstrate the safety of its product candidates, stating, in relevant part:

Our pre-clinical and clinical trials may fail to demonstrate acceptable levels of safety, efficacy, and quality of our product candidates, including those based on our PMO-based technologies, which could prevent or significantly delay their regulatory approval.

[. . .] Ongoing and future pre-clinical and clinical trials of our product candidates may not show sufficient safety, efficacy or adequate quality to obtain or maintain regulatory approvals. For example, although the pre-clinical data for PPMO collected to date is promising, the additional data we collect, including in the clinic, may not be consistent with the pre-clinical data or show a safe benefit that warrants further development or pursuit of a regulatory approval for PPMO product candidates. Furthermore, success in pre-clinical and early clinical trials does not ensure that the subsequent trials will be successful, nor does it predict final results of a confirmatory trial. For example, we cannot provide assurances that data from our EXONDYS 51 ongoing studies will be positive and consistent through the study periods or that the interpretation by regulators, such as the FDA or EMA, of the data we collect for our product candidates will be consistent with our interpretations. If our study data do not consistently or sufficiently demonstrate the safety or efficacy of any of our product candidates, including for those that are based on our PMO-based technologies, then the regulatory approvals for such product candidates could be significantly delayed as we work to meet approval requirements, or, if we are not able to meet these requirements, such approvals could be withheld or withdrawn.

(Emphasis in original.) This risk warning was plainly a generic “catch-all” provision that was not tailored to Sarepta's actual known risks with respect to golodirsen's safety profile.

29. Appended as exhibits to the 2017 10-K were signed certifications pursuant to the Sarbanes-Oxley Act of 2002 (“SOX”), wherein the Individual Defendants certified that “the [2017 10-K] fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in [the 2017 10-K] fairly presents, in all material respects, the financial condition and results of operations of Sarepta Therapeutics, Inc.”

30. On March 12, 2018, Sarepta issued a press release announcing the Company's plan to submit an NDA to the FDA for accelerated approval of golodirsen in patients with DMD amenable to skipping exon 53 (the "March 2018 Press Release"). In the March 2018 Press Release, Sarepta touted the results of the 4053-101 Study, highlighted how "[t]he Company met with the FDA Division of Neurology Products in February to obtain guidance on the regulatory pathway for golodirsen," and utterly failed to mention any possible or known risks related to golodirsen. Instead, the March 2018 Press Release merely stated that the 4053-101 Study had "assess[ed] the safety [and] tolerability . . . of golodirsen," and that, based on the results of that study and the FDA's guidance, the Company would move towards completing a rolling submission of an NDA for golodirsen by year-end 2018. Specifically, the March 2018 Press Release stated, in relevant part:

Sarepta . . . recently received final minutes from a February 2018 Type C meeting held with the Division of Neurology Products, United States Food and Drug Administration (the Division), to solicit the Division's guidance on the development pathway for Sarepta's therapeutic candidate, golodirsen[.]

* * *

As previously announced in the third quarter of 2017, Sarepta's 4053-101 study – a Phase 1/2 study to assess the safety, tolerability, pharmacokinetics and efficacy of golodirsen in 25 boys with confirmed deletions of the DMD gene amenable to exon 53 skipping – demonstrated statistically significant results in favor of golodirsen on all biological endpoints[.]

Based on the results of Study 4053-101 and informed now by FDA's feedback, Sarepta intends to complete a rolling submission of a golodirsen NDA by year-end 2018, seeking accelerated approval of golodirsen based on an increase in dystrophin protein as a surrogate endpoint.

31. The March 2018 Press Release also quoted Defendant Ingram, who touted how the FDA Neurology Division had essentially outlined Sarepta's path to success for the proposed golodirsen NDA, stating that the FDA Neurology Division's guidance had been "thoughtful and

direct . . . regarding golodirsén,” and that the FDA Neurology Division had “engage[d] and provide[d] clear direction to [Defendants] on the steps necessary to support an NDA submission for accelerated approval.”

32. Finally, the March 2018 Press Release noted that the complete submission of Sarepta’s NDA for golodirsén would require “long-term animal toxicology studies, which will be completed in the fourth quarter of 2018.”

33. On December 20, 2018, Sarepta issued a press release announcing that it had completed submission of its NDA seeking approval of golodirsén in patients with DMD amenable to skipping exon 53 (the “December 2018 Press Release”). In the December 2018 Press Release, Sarepta again touted the results of the 4053-101 Study, touted the fact that the 4053-101 Study had assessed the safety and tolerability of golodirsén, and that the 4053-101 Study had been included in the Company’s NDA for golodirsén. Specifically, the December 2018 Press Release stated, in relevant part:

The completion of the rolling submission for golodirsén includes data from the 4053-101 study assessing the safety, tolerability, pharmacokinetics and dystrophin expression of golodirsén in 25 boys with confirmed deletions of the DMD gene amenable to exon 53 skipping. The study demonstrated statistically significant results in favor of golodirsén on all biological endpoints, including properly exon-skipped RNA transcript using reverse transcription polymerase chain reaction, increase in quantity of dystrophin expression from baseline using Western blot and increase in dystrophin intensity as measured by immunohistochemistry.

34. The December 2018 Press Release also failed to address what, if any, safety issues were indicated by golodirsén’s use based on prior and ongoing studies, even though the drug’s safety had been assessed in the 4053-101 Study and was being assessed on an ongoing basis in Sarepta’s ESSENCE study. Rather, the December 2018 Press Release touted that “[i]f the golodirsén NDA is filed and granted accelerated approval, the company’s ESSENCE study (4045-301) could serve as a post-marketing confirmatory study.”

35. Finally, the December 2018 Press Release quoted Defendant Ingram, who used the completed submission of the golodirsen NDA as another marketing opportunity for the drug and the PMO technology facilitating it, stating, in relevant part:

We are grateful for the patients and clinicians who have participated in the study with an aim to advance treatment for all patients with Duchenne Sarepta is committed to developing therapies to benefit the greatest possible percentage of patients affected by Duchenne. Our proprietary PMO technology remains central to our commitment to patients with Duchenne. Combined, EXONDYS 51® (eteplirsen), golodirsen, and casimersen, have the potential to treat nearly 30 percent of patients with Duchenne[.]

36. On February 14, 2019, Sarepta issued a press release announcing that the FDA's Neurology Division had accepted the Company's NDA "seeking accelerated approval for golodirsen (SRP-4053) and provided a regulatory action date of August 19, 2019" (the "February 2019 Press Release"). As with prior press releases from the Company, discussed above, the February 2019 Press Release touted the inclusion of Sarepta's data from the 4053-101 study assessing the safety and tolerability of golodirsen. Specifically, the February 2019 Press Release stated, in relevant part:

The company completed its NDA at the end of 2018 as part of a rolling submission and requested priority review, which was granted. The company previously received orphan drug designation for golodirsen. The NDA includes data from the 4053-101 study assessing the safety, tolerability, pharmacokinetics and dystrophin expression of golodirsen in 25 boys with confirmed deletions of the dystrophin gene amenable to exon 53 skipping. The study demonstrated statistically significant results in favor of golodirsen on all biological endpoints, including properly exon-skipped RNA transcript using reverse transcription polymerase chain reaction, increase in quantity of dystrophin expression from baseline using Western blot and increase in dystrophin intensity as measured by immunohistochemistry.

37. The February 2019 Press Release also utterly failed to address what, if any, safety issues were indicated by golodirsen's use based on prior and ongoing studies, even though the drug's safety had been assessed in the 4053-101 Study and was being assessed on an ongoing basis in Sarepta's ESSENCE study. Rather, the February 2019 Press Release touted that

“Sarepta’s ongoing ESSENCE study (4045-301), a global, randomized double-blind, placebo-controlled study assessing the safety and efficacy of golodirsen and casimersen, our exon 45 skipping agent,” could possibly serve as a post-marketing confirmatory study for golodirsen.

38. On February 28, 2019, Sarepta filed its Annual Report on Form 10-K with the SEC, reporting the Company’s financial and operating results for the fiscal year ended December 31, 2018 (the “2018 10-K”). The 2018 10-K largely regurgitated the positive information concerning golodirsen’s regulatory development as described in prior press releases, while again wholly failing to disclose what, if any, safety concerns were indicated by golodirsen’s use. Specifically, the 2018 10-K stated, in relevant part:

Golodirsen (SRP-4053) uses our PMO chemistry and exon-skipping technology to skip exon 53 of the DMD gene. Golodirsen is designed to bind to exon 53 of dystrophin pre-mRNA, resulting in exclusion, or “skipping”, of this exon during mRNA processing in patients with genetic mutations that are amenable to exon 53 skipping. We are enrolling and dosing patients in ESSENCE (4045-301), our Phase 3 placebo controlled confirmatory trial in patients who have a confirmed mutation of the DMD gene that is amenable to exon 45 or 53 skipping using casimersen and golodirsen, respectively. Golodirsen is also being evaluated in a Phase 1/2 trial having two parts. Part I of the Phase 1/2 trial has been completed, and Part II, an open-label portion of the trial, is expected to be completed in 2019 (Study 4053-101). In September 2017, we announced positive results of an analysis that included biopsies of the bicep muscle at baseline and on-treatment at the Part II, Week 48 time point. The 4053-101 interim trial results demonstrated statistical significance on all primary and secondary biological endpoints. In December 2018, we completed the submission of our rolling NDA to the FDA seeking accelerated approval for golodirsen. The FDA accepted the NDA and granted priority review status for golodirsen with a targeted regulatory action date of August 19, 2019. The FDA also indicated that it does not intend to conduct an advisory board for golodirsen.

39. The 2018 10-K also contained merely generic, boilerplate representations concerning the risk that Sarepta’s pre-clinical and clinical trials could fail to demonstrate acceptable levels of safety, which could prevent or significantly delay regulatory approval. Specifically, the 2018 10-K stated, in relevant part:

To obtain the requisite regulatory approvals to market and sell any of our product candidates, we must demonstrate, through extensive pre-clinical and clinical trials, that the product candidate is safe and effective in humans. [. . .]

Furthermore, success in pre-clinical and early clinical trials does not ensure that the subsequent trials will be successful, nor does it predict final results of a confirmatory trial. Some of our clinical trials were conducted with small patient populations and were not blinded or placebo-controlled, making it difficult to predict whether the favorable results that we observed in such trials will be repeated in larger and more advanced clinical trials Similarly, we cannot provide assurances that data from our studies with respect to EXONDYS 51, golodirsen, casimersen and other gene therapy-based product candidates will be positive and consistent through the study periods or that the interpretation by regulators, such as the FDA or EMA, of the data we collect for our product or product candidates will be consistent with our interpretations.

This risk warning was plainly a generic “catch-all” provision that was not tailored to Sarepta’s actual known risks with respect to golodirsen’s safety profile.

40. The 2018 10-K also contained merely generic, boilerplate representations related to the risk that Sarepta’s product candidates may cause undesirable side effects or have other properties that could delay or prevent regulatory approval of product candidates. To this end, the 2018 10-K stated, in relevant part:

Our product candidates may cause undesirable side effects. In addition to side effects caused by product candidates, the administration process or related procedures also can cause adverse side effects. If any such adverse events occur in our trials, we may decide, or the FDA, the EMA or other regulatory authorities could order us, to halt, delay or amend preclinical development or clinical development of our product candidates or we may be unable to receive regulatory approval of our product candidates for any or all targeted indications. Even if we are able to demonstrate that all future serious adverse events are not product-related, such occurrences could affect patient recruitment or the ability of enrolled patients to complete the trial. Moreover, if we elect, or are required, to delay, suspend or terminate any clinical trial of any of our product candidates, the commercial prospects of such product candidates may be harmed and our ability to generate product revenues from any of these product candidates may be delayed or eliminated. Any of these occurrences may harm our ability to develop other product candidates and may harm our business, financial condition and prospects significantly.

This risk warning, too, was plainly a generic “catch-all” provision that was not tailored to Sarepta’s actual known risks with respect to golodirsen’s safety profile.

41. Finally, the 2018 10-K contained merely generic, boilerplate representations concerning the risk that Sarepta’s drug candidate NDAs could be denied or face significant delays, which could have a material negative impact on the Company’s business, stating, in relevant part:

Our ability to obtain the government or regulatory approvals required to commercialize any of our product candidates in any jurisdiction, including in the U.S. or the EU, cannot be assured, may be significantly delayed or may never be achieved for various reasons including the following:

* * *

- The regulatory approval process for product candidates targeting orphan diseases, such as DMD, that use new technologies and processes, such as antisense oligonucleotide therapies, gene therapy and other alternative approaches or endpoints for the determination of efficacy is uncertain due to, among other factors, evolving interpretations of a new therapeutic class, the broad discretion of regulatory authorities, lack of precedent, small safety databases, varying levels of applicable expertise of regulators or their advisory committees, scientific developments, changes in the competitor landscape, shifting political priorities and changes in applicable laws, rules or regulations and interpretations of the same. As a result of uncertainty in the approval process for products intended to treat serious rare diseases, we may not be able to anticipate, prepare for or satisfy requests or requirements from regulatory authorities, including completing and submitting planned NDAs, BLAs and MAAs for our product candidates, in a timely manner, or at all. Examples of such requests or requirements could include, but are not limited to, conducting additional or redesigned trials and procedures (e.g., additional safety data, patient muscle biopsies, dystrophin analyses and using different assays), repeating or completing additional analysis of our data, or providing additional supportive data. In addition, in the U.S., an FDA advisory committee or regulators may disagree with our data analysis, interpretations and conclusions at any point in the approval process, which could negatively impact the approval of our NDA or BLA or result in a decision by the Company not to proceed with an NDA or BLA submission for a product candidate based on feedback from regulators.

This risk warning was yet another example of a plainly generic “catch-all” provision that was not tailored to Sarepta’s actual known risks with respect to golodirsen’s safety profile.

42. Appended as exhibits to the 2018 10-K were signed SOX certifications, wherein the Individual Defendants certified that “the [2018 10-K] fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in [the 2018 10-K] fairly presents, in all material respects, the financial condition and results of operations of Sarepta Therapeutics, Inc.”

43. The statements referenced in ¶¶ 24-42 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company’s business, operational and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) golodirsén posed significant safety risks to patients; (ii) consequently, the NDA package for golodirsén’s accelerated approval was unlikely to receive FDA approval; and (iii) as a result, Sarepta’s public statements were materially false and misleading at all relevant times.

The Truth Begins to Emerge

44. On August 19, 2019, post-market, Sarepta issued a press release announcing receipt of a CRL from the FDA regarding the Company’s NDA seeking accelerated approval of golodirsén for the treatment of DMD (the “August 2019 Press Release”). Specifically, the August 2019 Press Release stated, in relevant part:

Sarepta . . . received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding the New Drug Application (NDA) seeking accelerated approval of golodirsén injection for the treatment of Duchenne muscular dystrophy (DMD) in patients with a confirmed mutation amenable to exon 53 skipping.

The CRL generally cites two concerns: the risk of infections related to intravenous infusion ports and renal toxicity seen in pre-clinical models of golodirsén and observed following administration of other antisense oligonucleotides. Renal toxicity with golodirsén was observed in pre-clinical models at doses that were ten-fold higher than the dose used in clinical studies. Renal toxicity was not observed in Study 4053-101, on which the application for golodirsén was based.

* * *

Sarepta will immediately request a meeting with the FDA to determine next steps.

45. On this news, Sarepta's stock price fell \$18.24 per share, or 15.16%, to close at \$102.07 per share on August 20, 2019.

46. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

47. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Sarepta securities during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

48. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Sarepta securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Sarepta or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

49. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

50. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

51. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the federal securities laws were violated by Defendants' acts as alleged herein;
- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Sarepta;
- whether the Individual Defendants caused Sarepta to issue false and misleading financial statements during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;
- whether the prices of Sarepta securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

52. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

53. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- the omissions and misrepresentations were material;
- Sarepta securities are traded in an efficient market;
- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;
- the Company traded on the NASDAQ and was covered by multiple analysts;
- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and
- Plaintiff and members of the Class purchased, acquired and/or sold Sarepta securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

54. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

55. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

COUNT I

(Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants)

56. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

57. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

58. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Sarepta securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Sarepta securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

59. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Sarepta securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Sarepta's finances and business prospects.

60. By virtue of their positions at Sarepta, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended

thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

61. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As the senior managers and/or directors of Sarepta, the Individual Defendants had knowledge of the details of Sarepta's internal affairs.

62. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of Sarepta. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Sarepta's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Sarepta securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Sarepta's business and financial condition which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Sarepta securities at artificially inflated prices and relied upon the price of the securities,

the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.

63. During the Class Period, Sarepta securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Sarepta securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of Sarepta securities was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Sarepta securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

64. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

65. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II

(Violations of Section 20(a) of the Exchange Act Against The Individual Defendants)

66. Plaintiff repeats and re-alleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

67. During the Class Period, the Individual Defendants participated in the operation and management of Sarepta, and conducted and participated, directly and indirectly, in the conduct of Sarepta's business affairs. Because of their senior positions, they knew the adverse non-public information about Sarepta's misstatement of income and expenses and false financial statements.

68. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Sarepta's financial condition and results of operations, and to correct promptly any public statements issued by Sarepta which had become materially false or misleading.

69. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Sarepta disseminated in the marketplace during the Class Period concerning Sarepta's results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Sarepta to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of Sarepta within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Sarepta securities.

70. Each of the Individual Defendants, therefore, acted as a controlling person of Sarepta. By reason of their senior management positions and/or being directors of Sarepta, each of the Individual Defendants had the power to direct the actions of, and exercised the same to

cause, Sarepta to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Sarepta and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

71. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Sarepta.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

- A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;
- B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;
- C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and
- D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

Dated: August 30, 2019

Respectfully submitted,

POMERANTZ LLP

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Attorneys for Plaintiff

**gtCERTIFICATION PURSUANT
TO FEDERAL SECURITIES LAWS**

1. I, Andrew Salinger, make this declaration pursuant to Section 27(a)(2) of the Securities Act of 1933 ("Securities Act") and/or Section 21D(a)(2) of the Securities Exchange Act of 1934 ("Exchange Act") as amended by the Private Securities Litigation Reform Act of 1995.

2. I have reviewed a Complaint against Sarepta Therapeutics, Inc. ("Sarepta" or the "Company") and authorize the filing of a comparable complaint on my behalf.

3. I did not purchase or acquire Sarepta securities at the direction of plaintiffs counsel, or in order to participate in any private action arising under the Securities Act or Exchange Act.

4. I am willing to serve as a representative party on behalf of a class of investors who purchased or acquired Sarepta securities during the class period, including providing testimony at deposition and trial, if necessary. I understand that the Court has the authority to select the most adequate lead plaintiff in this action.

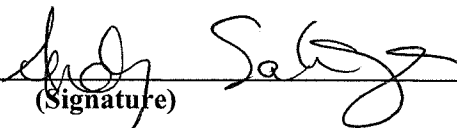
5. To the best of my current knowledge, the attached sheet lists all of my transactions in Sarepta securities during the Class Period as specified in the Complaint.

6. During the three-year period preceding the date on which this Certification is signed, I have not sought to serve as a representative party on behalf of a class under the federal securities laws.

7. I agree not to accept any payment for serving as a representative party on behalf of the class as set forth in the Complaint, beyond my pro-rata share of any recovery, except such reasonable costs and expenses directly relating to the representation of the class as ordered or approved by the Court.

8. I declare under penalty of perjury that the foregoing is true and correct.

Executed 8.22.19
(Date)


(Signature)

Andrew Salinger
(Type or Print Name)

Sarepta Therapeutics, Inc. (SRPT)

Salinger, Andrew

List of Purchases and Sales

Date	Purchase or Sale	Number of Shares/Unit	Price Per Share/Unit
6/19/2018	Purchase	30	\$163.9700
10/2/2018	Purchase	40	\$142.3800
4/8/2019	Purchase	44	\$124.6400
8/16/2019	Purchase	16	\$124.2400
8/16/2019	Purchase	46	\$124.3500
8/16/2019	Purchase	50	\$125.6900
8/16/2019	Purchase	50	\$123.1372